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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,554	05/22/2000	Brett P. Monia	ISPH-0463	1277

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66 E Main Street
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EXAMINER

FREDMAN, JEFFREY NORMAN

ART UNIT	PAPER NUMBER
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1634

21

DATE MAILED: 12/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/575,554

Applicant(s)

MONIA ET AL.

Examiner

Jeffrey Fredman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 7-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 7-10 is/are rejected.
- 7) ☒ Claim(s) 11-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Status

Claims 1 and 7-20 are pending.

This application had rejections which were reversed by the Board of Patent Appeals and Interferences (BPAI). Ordinarily, this would represent a simple allowance, but the BPAI at page 6 of their decision expressly stated that Bos et al (U.S. Patent 5,591,582) teaches two oligonucleotides of SEQ ID Nos: 26 and 28, but did not make the new grounds of rejection themselves. Consequently, the following rejections are made per the suggestion of the BPAI. Claims drawn to oligonucleotides other than SEQ ID NO: 26 and 28 will be indicated allowable since the prior rejections were reversed by the BPAI.

This action is NON-FINAL since it makes new rejections necessitated by the suggestions of the Board of Patent Appeals and Interferences.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1 and 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Bos et al (U.S. Patent 5,591,582).

Bos teaches an oligonucleotide, oligomer K-12, which is identical to SEQ ID NO: 26 (see column 19) except that it is shorter by one base at the 5' end. Bos further teaches an oligomer K-61 which is identical to SEQ ID NO: 28 (see column 19) except that it is shorter by one base at the 5' end. Based upon the BPAI decision, these oligonucleotides are 21 mers that comprise 8 nucleobases of SEQ ID Nos: 26 and 28.

With regard to claim 10, Bos teaches ordinary oligonucleotide synthetic modes in which oligonucleotides are placed in water, which is a pharmaceutically acceptable carrier (see column 8, line 30).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7, 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bos et al (U.S. Patent 5,591,582) in view of Ott et al (Biochemistry (1987) 26:8237-8241).

Bos teaches an oligonucleotide for mutagenesis, oligomer K-12, which is identical to SEQ ID NO: 26 (see column 19) except that it is shorter by one base at the 5' end. Bos further teaches an oligomer K-61 which is identical to SEQ ID NO: 28 (see column 19) except that it is shorter by one base at the 5' end. Based upon the BPAI decision, these oligonucleotides are 21 mers that comprise 8 nucleobases of SEQ ID Nos: 26 and 28.

With regard to claim 10, Bos teaches ordinary oligonucleotide synthetic modes in which oligonucleotides are placed in water, which is a pharmaceutically acceptable carrier (see column 8, line 30).

Bos does not teach backbone modifications.

Ott teaches modification of primers for mutagenesis by the addition of phosphorothioate (see page 8237, column 1). These modified primers have the altered backbone which comprises at phosphorothioate, to result in chimeric DNA and phosphorothioate backbone oligonucleotides (see page 8237, column 2).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the oligonucleotides of Bos with the phosphorothioate of Ott since Ott teaches "Three phosphorothioates at the 5' termini of the primer, however, give sufficient protection as judged by the mutation yields (see page 8240, column 1)." Thus Ott is teaching that while ordinary DNA such as that of Bos is cleaved by Klenow prior to mutagenesis, the phosphorothioate labeled DNA of

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Ott improves the mutagenesis by preventing cleavage by Klenow. So an ordinary practitioner interested in mutagenesis would have been motivated by Ott to incorporate phosphorothioate into the mutagenic primer in order to protect the primer from Klenow.

6. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bos et al (U.S. Patent 5,591,582) in view of Manoharan et al (Tetrahedron Letters (1991) 32:7171-7174).

Bos teaches an oligonucleotide for mutagenesis, oligomer K-12, which is identical to SEQ ID NO: 26 (see column 19) except that it is shorter by one base at the 5' end. Bos further teaches an oligomer K-61 which is identical to SEQ ID NO: 28 (see column 19) except that it is shorter by one base at the 5' end. Based upon the BPAI decision, these oligonucleotides are 21 mers that comprise 8 nucleobases of SEQ ID Nos: 26 and 28.

With regard to claim 10, Bos teaches ordinary oligonucleotide synthetic modes in which oligonucleotides are placed in water, which is a pharmaceutically acceptable carrier (see column 8, line 30).

Bos does not teach 2' modifications.

Manoharan teaches modification of the 2' position of primers to permit labeling (see abstract).

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify the oligonucleotides of Bos with the 2' labeling of Manoharan since Manoharan teaches "nucleic acid probe-based diagnostics are two important areas of current interest in the field of nucleic acid chemistry (see page

7171)." Manoharan suggests that the 2' modification is desirable for labeling of the nucleic acid and Bos expressly wishes a labeled oligonucleotide (see for example, column 2, line 55). Therefore, an ordinary practitioner would have been motivated to label the nucleic acid of Bos as taught by Manoharan in order to achieve the goals of nucleic acid detection of Bos and Manoharan.

Allowable Subject Matter

7. Claims 11-20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. These claims are allowable because the BPAI chose to reverse the rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is currently 703-308-6568. In mid January, 2004, when TC 1600 relocates to the new USPTO facility in Alexandria, the examiner's phone number will become 571-272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The supervisor's new telephone number in mid January will be 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is currently 703-872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

A handwritten signature in black ink, appearing to read 'Jeffrey Fredman', with a long, sweeping horizontal stroke extending to the right.

Jeffrey Fredman
Primary Examiner
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